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Pharmaceutical Division

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June 5, 2000

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Attn: Docket Number 00N-1266

Dear Sir or Madam,

Bayer Corporation wishes to thank the FDA for the opportunity to comment on the pediatric exclusivity program established through the FDA Modernization Act of 1997. As a major healthcare company with a longstanding interest in access to important medicines for all populations, Bayer is dedicated to the appropriate study of pharmaceutical drugs in the pediatric population.

We were pleased when ciprofloxacin was included in the "List of Drugs for Which Additional Information May Produce Health Benefits in the Pediatric Population" in early 1998. We also appreciated the FDA's efforts which led to the Guidance for Industry : Qualifying for Pediatric Exclusivity Under Section 505A of the Federal Food, Drug and Cosmetic Act" published in June 1998. As such, Bayer began discussions with the staff at the Division of Special Pathogens and Immunologic Drug Products to allow for the initiation of clinical trials in children.

We submitted, in August, 1998, a proposed pediatric request for a comparative trial of ciprofloxacin versus an appropriate comparator in patients with complicated urinary tract infections, a disease in which ciprofloxacin has had a long history of established safety and efficacy in the adult population. Discussions continued for several months, culminating in a Written Request letter issued on May 12, 1999. Bayer's experience in the negotiation leading to the Written Request and in the subsequent study implementation leads us to the following findings:

There clearly are operational difficulties inherent in the study of certain classes of drugs and diseases in pediatric populations which necessitate the establishment of reasonable study objectives and commitment targets. Concepts employed for development of drugs in adult populations (such as sample size requirements and studies in special patient sub-groups) do not necessarily translate to efficient development in children. A requirement for multiple blood draws in children as part of pharmacokenetic studies, for example, has a chilling effect on the ability of investigators to enroll study patients. Also, parental concern over enrolling children into trials, especially when alternate proven therapies are available, is a considerable challenge in fulfilling enrollment commitments.

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If commitment targets established by FDA fail to recognize the difficulties in achieving pediatric enrollment, it may be impractical for the sponsoring drug company to achieve these targets. The study thereby will fail to meet the conditions for approval of the pediatric indication and both the sponsor and the FDA will fall short of meeting the objectives of the FDAMA pediatric initiative to the public detriment.

The intent of Congress in establishing the pediatric initiative was to use the exclusivity provision to learn about the impact of various medicines on children and to encourage their safe use. In many cases, the pediatric studies will serve to confirm or refute the off-label pediatric use of drugs approved in adult populations. In any case, the study results will better inform prescribers as to the risks inherent in the use of adult medication in children.

The FDAMA pediatric exclusivity program provides an important incentive to sponsors to appropriately study drugs in the pediatric setting. If, however, sponsors find it impractical to implement the studies, or impossible to meet the conditions established by the FDA in the Written Request letter, they may choose to discontinue the studies or to not undertake them at all. Under either of these circumstances, the objectives of FDAMA would not be achieved.

We hope that as sponsors and the FDA gain additional experience in the design and conduct of pediatric trials that the difficulties mentioned herein may become less problematic. In the meantime, we feel it important that sponsors and the FDA commit to an open dialogue on implementation, and that flexibility be demonstrated by FDA in recognition of the sponsor's due diligence in attempting to meet study conditions. This kind of partnership between industry and the FDA is necessary in order for pediatric programs to be successful and for FDAMA objectives to be achieved.

Bayer Corporation remains committed to pediatric initiatives, and to working with the FDA in improving the process for studying and developing drugs for the pediatric population. We hope that this response to the FDA's request for comments on these initiatives positively contributes to such a dialogue.

Sincerely,

Carl Calcagni, R.Ph
Vice President, Regulatory Affairs

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